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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BIOGEN '755 PATENT LITIGATION	Civil Action No.: 10-cv-02734(CCC)(MF) Honorable Claire C. Cecchi **SERONO'S REPLY IN SUPPORT OF RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW**

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I. THE CLAIMS OF THE '755 PATENT ARE NOT PATENT-ELIGIBLE

1. *Alice/Mayo* Step 1: The Claims Cover the Use of a Product of Nature

The '755 patent covers using IFN-β's antiviral activity—an innate feature and a natural phenomenon—to treat viruses just as IFN-β naturally produced by human cells had been used in the prior art. ECF No. 983 at 4, 7. Biogen's expert conceded it is "very clear on the face of the patent" that the claims fail to provide any "new method of treatment," new "information about [such] treatment," or "new method[] of administration" over what was ***already known*** in "the 1970s" about using IFN-β. Ex. 1, 2/20/18 AM Tr. (Green) 176:2–4, 176:18–22, 204:15–18; *see also id.* at 174:11–175:14. Biogen does not dispute these facts. ECF No. 989 at 11–17.

It is also undisputed that IFN-β polypeptides, whether or not produced recombinantly, contain identical informational content: the linear sequence of amino acids. ECF No. 983 at 6. The Supreme Court and the Federal Circuit have made clear that where, as here, patent claims "d[o] not create or alter any of the genetic information" that exists in nature, the claims are ineligible. *Ass'n for Molecular Pathology v. Myriad*, 133 S. Ct. 2107, 2116 (2013); *In re Roslin Inst.*, 750 F.3d 1333, 1337 (Fed. Cir. 2014) (claims ineligible that "'did not create or alter any of the genetic information' of [the recited] clones") (quoting *Myriad*, 133 S. Ct. at 2116).

Biogen's argument that there are "minor differences in the structures of the sugars" of IFN-β produced naturally versus recombinantly (ECF No. 989 at 16), even were it true, would change nothing. The Federal Circuit has rejected such arguments, holding that any "minor . . . differences" between a product of nature and its copy are "irrelevant" to the eligibility inquiry. *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1377 n.3 (Fed. Cir. 2016); *see also Roslin*, 750 F.3d at 1337, 1339. In *Merial*, the court held ineligible method claims using synthetic DNA, rejecting the argument that the claims were inventive because they involved DNA having "altered methylation status," and holding that "its ***sequence*** [was] identical to that of naturally

occurring DNA," and that "any ***minor chemical differences*** [were] ***irrelevant***." 818 F.3d at 1372–73, 77 n.3 (quoting *Myriad*, 133 S. Ct. at 2118) (quotation marks omitted).[1] In *Roslin*, the court held ineligible claims to cloned mammals lacking "markedly different characteristics" from the originals, although the clones had different genetics from them and shorter lifespans. 750 F.3d at 1335, 1337, 1339. Here, the claims cover using an exact genetic copy of natural IFN-β, and Biogen failed to present any evidence of differences material to eligibility.

Biogen incorrectly argues that "[n]o case has ever held method-of-treatment claims ineligible for patenting," suggesting that method of treatment claims are per se patent-eligible. ECF No. 989 at 2; *see also id.* at 12. That is false. A court in this District has held ineligible claims to using "DPP-IV inhibitors for treating and/or preventing metabolic diseases, particularly diabetes . . . in [a] targeted population." *Boehringer Ingelheim Pharm., Inc. v. HEC Pharm Co., Ltd.*, No. 15-cv-5982-PGS-TJB, 2016 WL 7177704, at *1, 12–13 (D.N.J. Dec. 8, 2016). The same is true elsewhere. *Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distr., Inc.*, No. 15-170-GMS, 2017 WL 3867649, at *16 (D. Del. Sept. 5, 2017), *appeal filed*, No. 18-1019 (Fed. Cir.) ("method of treating patients with" nitric oxide gas); *Endo Pharm. Inc. v. Actavis Inc.*, No. 14-1381-RGA, 2015 WL 7253674, at *3 (D. Del. Nov. 17, 2015), *appeal filed*, Nos. 17-1240, 17-1094 (Fed. Cir.) ("method of treating pain by giving a patient an oxymorphone dosage form").

Biogen also incorrectly argues that, based on the PTO's December 16, 2014 guidance on "Nature-Based Products," the PTO views such claims as "patent eligible." ECF No. 989 at 13–14. Since issuing that guidance, the PTO often has ***rejected*** method of treatment claims under Section 101. *See, e.g.*, *Ex parte Atwood*, Appeal No. 2015-001611, 2016 WL 4410483, at *6–8 (P.T.A.B. Aug. 16, 2016) (Alzheimer's disease); *Ex parte Chettier*, Appeal No. 2016-003639,

[1] Emphasis supplied throughout unless otherwise noted.

2016 WL 4487978, at *4–6 (P.T.A.B. Aug. 23, 2016), *reh'g denied*, 2017 WL 150032 (Jan. 11, 2017) (degenerative disc diseases); *Ex parte Chamberlain*, Appeal No. 2014-009849, 2017 WL 244123, at *3–6 (P.T.A.B. Jan. 18, 2017) (osteoporosis).

2. *Alice/Mayo* Step 2: The Claims Do Not Contain an Inventive Concept

The claims provide no unconventional manipulation of or improvement to the known methods of treating viruses with IFN-β. Biogen argues that Dr. Fiers provided recombinant IFN-β with biological activity. ECF No. 989 at 18. But IFN-β's activity is a natural phenomenon, which Biogen did not discover and which the '755 patent states was in the prior art. STX-0001 at .0020 (2:17–31). Biogen did not apply that phenomenon in a new or unconventional manner, instead using IFN-β to treat viruses just as it does in nature and as it was used in the prior art.

The '755 patent claims are unlike those in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, which provided a "***safer***" treatment "by ***lowering the risk*** of . . . prolongation" of "the time between the Q and T waves of the heart rhythm" that was associated with the drug iloperidone. 887 F.3d 1117, 1121 n.2, 1136 (Fed. Cir. 2018). They also are unlike the claims in *Rapid Litigation Management Ltd. v. Cellzdirect*, to a "***new and improved way*** of preserving hepatocyte cells," yielding benefits like "***improving*** the cells' viability after multiple freeze-thaw cycles" and "allow[ing] researchers to pool samples in advance and preserve them for later use." 827 F.3d 1042, 1048–50 (Fed. Cir. 2016). As Biogen's expert admitted, the '755 patent does not provide any "safer" or "new and improved way" of treating viruses with IFN-β. The claims instead "append[] routine, conventional steps to [the] natural phenomenon" of IFN-β's antiviral activity. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed. Cir. 2015).

3. Serono Did Not Waive Its Ineligibility Challenge

Biogen cites ***no authority*** to support its arguments that Serono was required "to ask the jury to decide" the legal issue of ineligibility or that Serono was required to raise it "before trial"

in some pre-trial motion or expert report. ECF No. 989 at 9–11.

Patent Eligibility Is Not a Jury Issue. ***No court*** has ***ever*** held that eligibility is a jury issue. ECF No. 989 at 9. Rather, eligibility indisputably is a legal question that courts routinely decide. *See, e.g.*, *Merial*, 818 F.3d at 1373; *Voter Verified, Inc. v. Election Sys. & Software LLC*, --- F.3d ---, 2018 WL 1882917, at *5 (Fed. Cir. Apr. 20, 2018). The Federal Circuit's recent decisions on which Biogen relies (ECF No. 989 at 7–8) ***confirm*** that the issue is a legal one for the courts to resolve. *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018); *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018); *Exergen Corp. v. Kaz USA, Inc.*, Nos. 2016-2315, 2016-2341, 2018 WL 1193529, at *6 (Fed. Cir. Mar. 8, 2018). Like the parties in this case (ECF No. 916 at 13), the parties in *Exergen* agreed in a pretrial order that the "question of invalidity under 35 U.S.C. § 101 is . . . a question of law to be decided by the court." No. 1:13-cv-10628-RGS, ECF No. 312-15 (App'x O, Joint Trial Mem.) at 2–3 (D. Mass. Jan. 4, 2016). The district court decided not to present the issue to the jury, deciding the legal question—***and any underlying factual disputes***—itself. No. 1:13-cv-10628-RGS, ECF No. 374 (1/21/16 Trial Transcript) at 244:21–245:2 (D. Mass Feb. 10, 2016). Consistent with this precedent, well-known model jury instructions lack any mention of eligibility. Exs. 12–15.

Contrary to Biogen (ECF No. 989 at 10), in *Contentguard Holdings, Inc. v. Apple Inc.* the court never held that ineligibility arguments cannot be made in a Rule 50 motion. Instead, the court stated that "[p]atent eligibility is a matter of law and is ***not*** properly submitted to a fact-finder such as a jury." No. 2:13-cv-1112-JRG, 2016 WL 1637280, at *6 (E.D. Tex. Apr. 25, 2016). Indeed, courts have ***rejected*** the same argument that Biogen makes here. In *ART+COM Innovationpool GmbH v. Google Inc.*, the plaintiff—like Biogen—argued that "Rule 50 is an improper vehicle for" raising ineligibility "because 'no question of patent-eligibility was

presented to the jury, and the jury was not instructed on patent-eligibility.'" No. 1:14–217–TBD, 2016 WL 10033420, at *2 (D. Del. Sept. 9, 2016). The court disagreed, holding that "there must be some way to raise a legal defense that was not presented to the jury, and [that] the ***most appropriate vehicle***" for raising eligibility "***appears to be a Rule 50(b) motion***." *Id.* Accordingly, issues of law regularly are vetted in a Rule 50 motion when not presented to the jury. *See Tortu v. Las Vegas Metro. Police Dep't*, 556 F.3d 1075, 1085 n.9 (9th Cir. 2009); *Varghese v. Honeywell Int'l, Inc.*, 424 F.3d 411, 423 (4th Cir. 2005).

No Requirement to Raise Ineligibility "Before Trial." Courts decide eligibility for the first time on a Rule 50 motion after a jury trial. *See, e.g., DDR Holdings, LLC v. Hotels.com, L.P.*, 954 F. Supp. 2d 509, 524–38 (E.D. Tex. 2013), *aff'd in part*, 773 F.3d 1245 (Fed. Cir. 2014). Biogen argues that Serono had to raise ineligibility in a pretrial motion or expert report (ECF No. 989 at 8–11), but fails to identify ***a single case*** in which a court held that a defendant waived this argument for such a reason. Rather, Biogen admits there was no unfair surprise, since Serono asserted ineligibility from the beginning of this case (in its counterclaims) through the end of it (in the pretrial order and in this motion). *Id.* at 8–9.

II. THE CLAIMS OF THE '755 PATENT ARE INVALID AS OBVIOUS

Dr. Taniguchi & Dr. Goeddel: At trial, Serono offered evidence that, prior to June 6, 1980, both Dr. Taniguchi and Dr. Goeddel made plasmids that were designed and expected to produce mature human IFN-β recombinantly in *E. coli*. ECF No. 983 at 11, 14. Biogen's witnesses conceded this, and Biogen did not address the evidence in opposing Serono's motion. Nor did Biogen address Serono's evidence that these plasmids ***actually produce*** IFN-β, as published in 1980, and that both Dr. Taniguchi and Dr. Goeddel have been widely lauded for that achievement. *Id.* at 11–15. Nor did Biogen address the evidence—again, that Biogen's witnesses conceded—that Dr. Taniguchi and Dr. Goeddel made more IFN-β than the Fiers lab

made, which undisputedly could have been scaled up, purified, formulated, and administered to treat viral diseases using routine methods known in the art before June 6, 1980. *Id.* at 13, 15.

Biogen's sole justification for the jury's verdict, relying on *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, addresses whether a reasonable juror could conclude on the basis of all of their experimental results that Drs. Taniguchi or Goeddel had made IFN-β before June 6, 1980. 40 F.3d 1223 (Fed. Cir. 1994). Biogen misapplies the relevant law. Prior invention under 35 U.S.C. § 102(g) can occur either 1) if the prior inventor "reduced to practice" his or her invention before the priority date of the challenged claims; or 2) if the inventor "conceived" of that invention before the priority date and then worked diligently from a time just before that date to the time of reduction to practice. *Mahurkar v. CR Bard, Inc*., 79 F.3d 1572, 1577 (Fed. Cir. 1996). Either way, both researchers are prior inventors of IFN-β made in *E. coli*.

Conception: Conception of a compound, including a polypeptide, requires "the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). The undisputed evidence shows that, prior to June 6, 1980, Dr. Taniguchi defined the amino acid sequence of mature IFN-β (STX-0014 at .0135), published it (STX-0023), and had a plan for obtaining it (PTX-0384 at 3). Ex. 2, 2/5/18 AM Tr. (Taniguchi) 16:17–17:10, 26:3–28:19, 119:3–13. Dr. Goeddel likewise knew of that sequence (having obtained it indirectly from Dr. Taniguchi), and had a plan for obtaining it, as his notebook notes (STX-0053 at .0003). Ex. 3, 2/2/18 Tr. Ex. C (Goeddel) 23:20–24:20, 25:8–26:3. This is the same mature human IFN-β polypeptide that both researchers sought to make and ultimately made. Biogen concedes that both researchers worked diligently both before and after June 6, 1980 (ECF No. 989 at 21–22). Both researchers worked until they submitted publications (Taniguchi's STX-0019 and Goeddel's STX-0054) that Dr.

Fiers, Biogen, and Biogen's witnesses admit disclose producing IFN-β. ECF No. 983 at 13, 15.

Reduction to Practice: The law requires evidence of "a successful experiment" to show that an invention has been reduced to practice. *Amgen*, 927 F.2d at 1206; *see also Purdue Pharma LP v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001); *Mycogen Plant Sci. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001); *Burroughs Wellcome*, 40 F.3d at 1229. Serono offered evidence that prior to June 6, 1980, both Dr. Taniguchi and Dr. Goeddel actually produced mature human IFN-β recombinantly in *E. coli* on multiple occasions. Biogen's witnesses conceded the positive results at trial (ECF No. 983 at 12), and in its opposition Biogen, admitted the same (ECF No. 989 at 21). Assuming one accepts Biogen's characterization of ***every other experiment*** as negative, the conclusion would not change that there was "a successful experiment" before June 6, 1980 establishing that Drs. Taniguchi and Goeddel reduced to practice recombinant IFN-β made in *E. coli* before that date.

The DNA Sequence of IFN-β: The DNA sequence for IFN-β undisputedly was in the prior art before June 6, 1980. Nor can there be a dispute that Biogen admitted that with that sequence in hand, it would have been "routine" for an ordinarily-skilled individual to both produce biologically active mature IFN-β recombinantly in *E. coli* and to administer it to treat tumors and viruses in exactly the same manner that IFN-β had been put to the exact same use in the prior art. *See, e.g.*, ECF No. 983 at 16–17. As predicted, Biogen's opposition tries to run away from these admissions. ECF No. 989 at 24–25. But that effort is impermissible under binding authority. *See, e.g., In re Cygnus Telecomms. Tech., LLC, Patent Litig.*, 56 F.3d 1343, 1347, 1354 (Fed. Cir. 2008); ECF No. 505-1 at 9, 12–13; ECF No. 595 at 7–11.

III. THE '755 PATENT FAILS TO ENABLE AND PROVIDE ADEQUATE WRITTEN DESCRIPTION FOR THE CLAIMS

Immunomodulation: Serono presented uncontroverted evidence that Dr. Fiers did not

describe any form of treatment with IFN-β by immunomodulation. ECF No. 983 at 22–23. Biogen understands that it has no evidentiary response to this argument, and thus seeks to change the subject by asserting that Serono and its witnesses applied an incorrect construction of "immunomodulation." ECF No. 989 at 29–31. This is false. Serono applied the definition the Court adopted: "regulation of the immune system by immunopotentiation (up-regulation) or immunosuppression (down-regulation)." ECF No. 968 at 17. Dr. Gutterman testified that he applied ***this exact construction***. Ex. 4, 2/7/18 AM Tr. (Gutterman) at 72:25 ("What [immuno-modulation] means is to regulate the immune system up or down . . . ."); *see also id.* at 36:22–23. Biogen's assertion that "the Court never held that immunomodulation means one or the other, but not both" (ECF No. 989 at 30) is beside the point. Serono never has argued otherwise. The problem with Biogen's claims is that the specification does not enable or describe ***therapeutically effective treatment*** by upregulation, downregulation, ***or*** both.

A person of ordinary skill expected that the only way to treat immune disorders was by up-regulation without down-regulation—or vice-versa—because causing both simultaneously would ***at once*** treat ***and aggravate*** such conditions. Ex. 4, 2/7/18 AM Tr. (Gutterman) 75:13–76:16. Yet, IFN-β indisputably upregulates and downregulates the immune system simul-taneously. ECF No. 983 at 22. The natural result of administering IFN-β to treat an immune condition would be, in part, to aggravate that condition, which cannot be "therapeutically effective" as the claims require. The only discussion of immunomodulation in the patent concerns cancer, which could be exacerbated by immunosuppression. STX-0001.0021 at 3:57–59. And as Dr. Gutterman repeatedly testified, there is nothing in the patent "that teaches how one would [immunomodulate] in a patient, nor is there any description of this." Ex. 4, 2/7/18 AM Tr. (Gutterman) 74:14–19; *see also id.* at 74:4–13; 74:20–76:16; 76:19–77:8, 82:1–3; Ex. 5,

2/7/18 PM Tr. (Gutterman) 37:12–24. Biogen failed to provide any contrary evidence.

Non-Human Hosts and Polypeptides: As Biogen correctly notes (ECF No. 989 at 26–27), and Serono agrees, the Court held that Biogen's method of treatment must be enabled and described. A trial has been held and evidence has been made of record demonstrating as a matter of law that the '755 patent's method claims are neither described nor enabled.

The claims of the '755 patent cover the administration of a broad scope of polypeptides made recombinantly in a broad scope of non-human hosts. STX-0001.0044–45. Among these polypeptides are fusions of *E. coli* to human amino acid sequences, as well as "uncountable" numbers of polypeptides fusing human IFN-β to proteins from other non-human hosts. Ex. 6, 2/8/18 PM Tr. (Lodish) 61:10–15; Ex. 5, 2/7/18 PM Tr. (Gutterman) 60:19–21. The jury heard evidence ***including from Biogen's witnesses*** that such fusion proteins would be therapeutically useless. Ex. 7, 1/25/18 Tr. (Derynck) 81:5–82:23; Ex. 1, 2/20/18 AM Tr. (Green) 172:23–173:21; Ex. 4, 2/7/18 AM Tr. (Gutterman) at 36:12–13, 68:22–71:7, 71:10–19, 71:23–72:15; Ex. 5, 2/7/18 PM Tr. (Gutterman) 59:4–15, 60:19–21; Ex. 6, 2/8/18 PM Tr. (Lodish) 61:10–15.

Biogen's response to this flaw is, in effect, that it would have been easy to test whether these polypeptides had *in vitro* biological activity once one made them. ECF No. 989 at 28–29. Even were this testing easy in June 1980—and Biogen's patentability argument hinges on the notion that it was not, *see, e.g., id.* at 18–19—it would require undue experimentation to screen these innumerable polypeptides to determine which would be therapeutically effective. *See Wyeth & Cordis Corp. v. Abbott Labs*, 720 F.3d 1380, 1385 (Fed. Cir. 2013) ("synthesiz[ing] and screen[ing] each of at least tens of thousands of candidate compounds" is undue experimentation, even "accept[ing] as true that one of ordinary skill could routinely use the assays disclosed in the specification to determine [therapeutic] effects in candidate compounds"). And even if one were

able to screen for *in vitro* activity, this would not mean that one could ***use*** the polypeptides in Biogen's ***method of treatment***. Dr. Fiers' fusion polypeptides may have shown biological activity, but they would have been therapeutically useless, as even Biogen's witnesses conceded.

Regarding the scope of host cells, Biogen asserts that "there were other non-human cells available in 1980" (ECF No. 989 at 28), citing testimony of Dr. Green. This argument misses the point. The parties agree that non-human host ***cells*** were available, but that fails to answer the key question: whether polypeptides ***produced*** in those cells, and thus methods of using them, were achievable without undue experimentation.[2] The unrebutted evidence is that they were not. *See, e.g.*, Ex. 8, 2/9/18 Tr. (Lodish) 92:13–17, 95:5–96:3. Biogen has admitted as much. STX-0002 at ¶ 63 ("The only hosts that were available [in 1979–80] for the expression of cloned DNA sequences were bacterial hosts."). The '755 patent did not even enable or describe the products at issue, since no one could make IFN-β in CHO cells in 1980 and no one then knew whether a product made in CHO would be therapeutically useful. Claims to ***methods of treatment*** using polypeptides that did not exist and could not be produced in 1980 are not enabled or described.

IV. PFIZER DOES NOT CONTRIBUTE TO INFRINGEMENT OF THE ASSERTED CLAIMS

Pfizer Does Not, and Cannot, Sell Rebif. To "sell" under Section 271 requires "the concept of a transfer of title or property." *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1319 (Fed. Cir. 2005). The undisputed evidence is that Pfizer has no right to "transfer . . . title or property" to Rebif to ***anyone***. ECF No. 983 at 23–24. Biogen offered no contrary evidence, instead arguing that the drug industry is unique because manufacturers do not sell directly to patients. *Id.* at 33–34. But Biogen cites ***no authority*** holding that the requirement for a "transfer

[2] Dr. Green's spin on Dr. Lodish's expert report from a prior case is incorrect. Dr. Lodish explained that the report referred "not to recombinant DNA expression of cloned genes, but rather to a technology that is very different." Ex. 9, 2/13/18 AM Tr. (Lodish) 59:16–60:25; *id.* at 61:1–4 ("not talking about recombinant protein production"); *id.* at 61:5–62:10.

of title or property" for a "sale" under Section 271 is any different here. Although Biogen cites dictum from *Milo & Gabby LLC v. Amazon.com*, 693 F. App'x 879, 886–87 (Fed. Cir. 2017), that "transfer of title does not have 'talismanic significance,'" (ECF No. 989 at 33), in *Milo* the Federal Circuit held that it ***would not*** "abandon[]" its "general insistence on transfer of title" as a requirement for a "sale" under Section 271. 693 F. App'x at 887.

Pfizer Does Not, and Cannot, Offer to Sell Rebif. Because Pfizer never had the right to sell Rebif, it could not possibly ***offer*** to sell Rebif. Biogen acknowledges that, for an alleged infringer to offer to sell, the infringer "must communicate[] a manifestation of willingness to ***enter into a bargain***, so made as to justify another person in understanding that his assent to that bargain is invited and will conclude it." ECF No. 989 at 35–36. Biogen's argument is contrary to the undisputed evidence at trial that Pfizer never had the right to "transfer title or property" or "enter into a bargain" regarding Rebif with ***anyone***. *Id.* at 35–37. The ***only*** cases on which Biogen relies are those in which a defendant ***actually had the right to sell the product***—unlike Pfizer. *Id.* at 36–37 (citing, *e.g.*, *3D Sys., Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1379 (Fed. Cir. 1998) (accused infringer had the right to sell); *Rudolph Techs., Inc. v. Camtek Ltd.*, No. 15-1246, 2015 WL 5039295, at *9 (D. Minn. Aug. 26, 2015) (same)).

V. THE EVIDENCE DOES NOT SUPPORT AN AWARD OF LOST PROFITS

Biogen's opposition ignores the Court's instruction that the jury "must take into account, where relevant, alternative actions that Serono would have undertaken had it not infringed." ECF No. 968 at 43. The evidence was undisputed that Serono would have exercised the license under the Option Agreement rather than infringe or leave the market. ECF No. 983 at 25. Biogen, thus, would not have made any of Serono's sales "but for" the alleged infringement, because Serono had an alternative action that would allow it to sell Rebif. *Id.* Biogen's ***only*** response is the specious claim that "Serono believed, when the '755 Patent issued, that the

Agreement did not even apply to sales of Rebif." ECF No. 989 at 39. The testimony Biogen cherry-picks reflects the fact that some witnesses understood that the Agreement applied only where there is infringement of a valid patent. ***No witness*** testified that, if the use of Rebif ***did*** infringe the '755 patent, Serono would not have exercised its option. The opposite is true. Ex. 10, 2/8/18 Tr. (Einav) 30:16–17 ("[I]f we found that we infringed the patent and the patent was valid, we would have certainly exercised the option."); Ex. 11, 1/31/18 Tr. (De Luca) 239:23–240:7 ("no doubt . . . we would have exercised the option").

Dated: May 9, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2018, true and correct copies of **SERONO'S REPLY IN SUPPORT OF RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW** was caused to be served via electronic mail and ECF upon all counsel of record.

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